Claims

1. A method for evaluating the efficacy of a therapeutic agent in the body of a mammal, wherein said agent acts to stimulate apoptosis, which comprises:

obtaining from a mammal to be treated with said therapeutic agent a sample of a body tissue in which tumor cells are present or a body fluid, wherein said tissue or fluid can contain a 17 kDa fragment of caspase 3, said fragment produced by specific cleavage of caspase 3 *in vivo*;

assaying said sample to determine the amount of said cleaved 17 kDa fragment of caspase 3 present;

administering said therapeutic agent to said mammal;

obtaining a second sample of said body tissue or said body fluid from said mammal; and

assaying said second sample to determine the amount of said 17kDa fragment of cleaved caspase 3 present;

wherein an increase in the amount of said 17 kDa fragment measured in said second sample over the amount measured in said first sample correlates with apoptosis stimulation and efficacy of said therapeutic agent.

2. The method of claim 1, wherein said body fluid is blood or a blood component.

3. The method of claim 2, wherein said blood component comprises plasma, serum or blood cells.

4. The method of claim 1, wherein said body fluid is saliva.

5. The method of claim 1, wherein said therapeutic agent comprises a chemotherapeutic agent, a radiotherapeutic

agent, a tumor suppressing nucleic acid, an oligonucleotide
or a combination thereof.

6. The method of claim 1, wherein said therapeutic
agent comprises a nucleic acid.

7. The method of claim 6, wherein said nucleic acid
comprises a DNA molecule which encodes a wild type p53
molecule, an RB molecule, an RB94 molecule, an apoptin
molecule or an antisense HER-2.

8. The method of claim 1, wherein said therapeutic
agent is administered as a complex with a ligand-cationic
liposome.

9. The method of claim 8, wherein said ligand
comprises transferrin, folate or an anti-transferrin
receptor single chain antibody fragment.

10. The method of claim 8, wherein said ligand
comprises an antibody or antibody fragment.

11. The method of claim 10, wherein said antibody or
antibody fragment binds to the transferrin receptor or to
HER-2.

12. The method of claim 10, wherein said antibody
fragment is an scFv fragment.

13. The method of claim 8, wherein said liposome
comprises a mixture of dioleoyltrimethylammonium phosphate
(DOTAP) and dioleoylphosphatidylethanolamine (DOPE) or
cholesterol or a combination thereof or a mixture of

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dimethyldioctadecylammonium bromide (DDAB) and DOPE or cholesterol or a combination thereof.

14. The method of claim 8, wherein said therapeutic agent further comprises a chemotherapeutic agent or a radiotherapeutic agent.

15. The method of claim 1, wherein the amount of said cleaved 17 kDa subunit in said second sample is at least 1.5 to about 2 times the amount of said cleaved subunit in said first sample.

16. A method for evaluating the efficacy of a therapeutic agent in the body of a mammal, wherein said agent acts to stimulate apoptosis, which comprises:
obtaining a sample of blood or a blood component from a mammal to be treated with said therapeutic agent;
assaying said sample to determine the amount of a 17 kDa fragment of caspase 3 present in said sample, said fragment produced by specific cleavage of caspase 3 *in vivo*;
administering said therapeutic agent to said mammal;
obtaining a second sample of blood or a blood component from said mammal; and
assaying said second sample to determine the amount of said 17kDa fragment of cleaved caspase 3 present in said sample;
wherein an increase in the amount of said 17 kDa fragment measured in said second sample over the amount measured in said first sample correlates with apoptosis stimulation and efficacy of said therapeutic agent.

17. The method of claim 16, wherein said blood component comprises plasma, serum or blood cells.

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18.   The method of claim 16, wherein said therapeutic agent comprises a chemotherapeutic agent, a radiotherapeutic agent, a tumor suppressing nucleic acid, an oligonucleotide or a combination thereof.